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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,205	05/15/2006	Ezio Bombardelli	2503-1186	5416

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,205	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 1-5, 7-8 are pending. Claims 1-5, 7-8 are examined on the merits. Claims 6 and 9 are canceled.

The declaration of Ezio Bombardelii filed Dec. 22, 2008 has been considered.

In view of the Appeal Brief filed on Dec. 22, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Terry A. McKelvey/

Supervisory Patent Examiner, Art Unit 1655

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-5, 7-8) in the reply filed on Jan 26, 2007 is acknowledged. The election of species is referred to Example 1 in the Specification, which are Salix rubra extract, Boswellia serrata extract, Green Tea extract, N-acetyl-glucosamine, Glucuronolactone, Enothera biennis oil.

Response to Arguments

The declaration under 37 CFR 1.132 filed 12/22/08 is insufficient to overcome the rejection of claims 1-5 and 7-8 as set forth below.

As stated previously, on page 2, Group 3, the boswellic acid is not the same as that claimed by Applicant. In the

claims, boswellic acid is from Boswellia serrata, while the affidavit is from Bowellia senolee. Furthermore, the boswellic acid is 20% of which 100 mg is used in the experiment. The 20% is not reflected in the claims. The claim is just 20-200 mg of Boswellica serrata extract.

Therefore, the affidavit of the composition having better than additive effects is not found to be convincing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 7-8 are indefinite because it is not clear what is exactly encompassed by "derivatives" of saligenin, boswellic acid, and lipophilic. Applicant's specification does not give a list of saligenin, boswellic acid, and lipophilic derivatives. Since applicant's definition of "derivative" is opened ended,

what is encompassed by "derivative" cannot be definitely determined. Numerous compounds could possibly be derived from saligenin, boswellic acid, and lipophilic including simple elements like carbon and hydrogen. It is not clear what compounds would still be considered "derivatives" in keeping with this limitation in the claims and what is taught in applicant's specification.

In addition, in Claim 1, it is not clear what is meant by the phrase "boswellic-acid-enriched Boswellia serrata extract." Does that mean boswellic acid concentration is increased or does it mean that boswellic acid has more specific desired compound in the Boswellic serrata extract?

Appropriate clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147) in view of Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571).

Foster teaches saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Saligenin is derived from salicin, which is the main component of Salix species (see page 231, right column, Studies on the Biopharmaceutical Quality and Pharmacokinetics, Chrubasik et al., 1998, Pain Digest, 8: 231-236).

However, it does not teach boswellic acid, procyanidins, N-acetyl-glucosamine, glucuronolactone, concentrations.

Taneja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5).

Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). The extract is used to treat condition of tissue inflammation, such as arthritis (column 3, lines 37-38, 54). Procyanidins can be isolated from green tea leaves, which are Camellia senesis (see Abstract, Nonaka et al., 1983, Chemical and Pharmaceutical Bulletin, 31, 3906-3914).

Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44).

Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating inflammation. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for treating inflammation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

The references teach ingredients for treating inflammation. Thus, an artisan of ordinary skill would reasonably expect that ingredients to treat inflammation could be used as the types

inflammation treatment composition taught by the references. This reasonable expectation of success would motivate the artisan to use saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, and D-glucuronolactone in the reference composition. Thus, using saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, and D-glucuronolactone is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for treatment of arthritis. However, the reference does teach the composition for treating inflammation, which is a symptom of arthritis. Foster teaches saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Taneja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5). Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8,

lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44). Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 1-5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) as applied to claims 1-4 above, and further in view of Chilton (US 6107334).

The teachings of Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) are set forth above and applied as before.

The combination of Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) do not specifically teach oenthera biennis.

Chilton teaches dietary supplement for ameliorating inflammatory disorders such as arthritis (column 1, lines 6-7, 39-40) with GLA, which is obtainable from oils of evening primrose (column 5, lines 52-54; column 6, lines 45-46) or Oenthera biennis (see

http://plants.usda.gov/java/profile?symbol=OEBI) and evening primrose is suitable as an ingestible pharmaceutical formulation (column 4, lines 15-16).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating inflammation. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for treating inflammation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than

the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

The references teach the ingredients to treat inflammation. Chilton teaches dietary supplement for ameliorating inflammatory disorders such as arthritis (column 1, lines 6-7, 39-40) with GLA, which is obtainable from oils of evening primrose (column 5, lines 52-54; column 6, lines 45-46). Thus, an artisan of ordinary skill would reasonably expect that ingredients to treat inflammation could be used as the types inflammation treatment composition taught by the references. This reasonable expectation of success would motivate the artisan to use saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, D-glucuronolactone, and oils of evening primrose in the reference composition. Thus, using saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, D-glucuronolactone, and oils of evening primrose is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for treatment of arthritis. However, the reference does teach the composition for treating inflammation, which is a symptom of arthritis. Foster teaches saligenin was used to treat rheumatism,

inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Graus et al. teaches treatment of osteoarthritis, which involved inflammation (column 1, lines 16, 22-25), with procyanidins (column 4, line 11), boswellic acids by extracting Boswellia serrata at least 15%, between 10-1000 mg per day (column 4, lines 31-40). Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44). Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to

employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655